UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF JOINT MOTION TO EXCLUDE OPINIONS OF EDWARD H. KAPLAN, M.D.

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INTRODUCTION

Defendants' Joint Motion to Exclude Dr. Kaplan's medical-monitoring opinions (ECF 20242, "Motion") established that Dr. Kaplan did not perform any independent investigation to determine whether his invasive medical-monitoring program would even benefit asymptomatic individuals such as those in Plaintiffs' proposed class, let alone whether such a program is "necessary." Instead, he offers a litigation-driven opinion based on his own *ipse dixit*. Plaintiffs are unable to refute these realities, which render his opinions inadmissible under Rule 702 and *Daubert*.

Plaintiffs argue in their Opposition (ECF 2072, "Opposition"), that Dr. Kaplan should be permitted to testify that the litany of tests he proposes are necessary for all valsartan patients based exclusively on the opinions of other experts. However, none of those experts evaluated the risks or benefits of Dr. Kaplan's proposed tests and, in any event, an expert cannot simply rely on the opinions of others.

Plaintiffs also fail to demonstrate that Dr. Kaplan has the background and specialized expertise that would qualify him to design a reliable public medical-monitoring program. Plaintiffs point to Dr. Kaplan's experience monitoring and treating patients at risk for cancer or cancer recurrence, but Dr. Kaplan's work as a treating oncologist does not qualify him to opine that a large group of asymptomatic individuals with no cancer diagnosis who were purportedly exposed to a probable human carcinogen should receive monitoring that deviates from established and

well-accepted guidelines for cancer screening protocols. For these reasons, and those stated in Defendants' Motion, Dr. Kaplan's opinions should be excluded.

ARGUMENT

I. DR. KAPLAN HAS NO RELIABLE BASIS FOR HIS OPINION THAT THE SCREENING PROGRAM HE PROPOSES IS "REASONABLE" OR "NECESSARY."

1. Dr. Kaplan's Medical-Monitoring Opinions Are Unreliable Because They Are Based Solely on the Opinions of Other Experts.

Plaintiffs argue at length that this Court should allow Dr. Kaplan to rely solely on the opinions of Plaintiffs' other experts in proposing a medical-monitoring regime. (Opp. at 11-16.) But, as explained in Defendants' Motion, a methodology that is grounded in "unblinking reliance" on other experts' opinions is inadmissible under *Daubert*. *In re TMI Litig*., 193 F.3d 613, 716 (3d Cir. 1999). "The crucial issue is whether [the expert] independently evaluated or verified the opinions upon which he relies." *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 274 (E.D. La. 2014). Dr. Kaplan fails that test.

To support his opinion that all members of the proposed class require the slew of medical tests proposed in his Report, Dr. Kaplan relies exclusively on the opinions held by Plaintiffs' other experts that all class members have reached the purported Lifetime Cumulative Threshold ("LCT") exposure to NDMA and/or NDEA as a result of their valsartan use and are therefore at increased risk of cancer. Dr. Kaplan did not explore the research or literature underlying those opinions. Indeed, Dr.

Kaplan admitted at his deposition that he made no attempt to investigate or confirm the purported increased cancer risk associated with nitrosamine exposure, much less to investigate or confirm that it warrants the medical monitoring he proposes:

> Q. Sure. You can't point to any medical literature or authoritative source that has actually determined that exposure to NDMA or NDEA reasonably necessitates the kind of medical monitoring for cancer in humans, can you?
>
> A. I haven't investigated that. I know literature exists because the reports that have come out were based on it. Plus I know the FDA withdrew the drug in a -- in a rapid manner because of their determination there was some risk. **That's all I know**.

(Kaplan Deposition, Mot. Ex. 2 ("Kaplan Dep."), 100:2-13) (emphasis added)). This blind reliance on the opinions of Plaintiffs' other experts is particularly concerning because Dr. Kaplan is misinformed about the relevant facts: as noted in the Motion, the FDA did *not* withdraw valsartan from the market; Defendants voluntarily recalled some of their valsartan products. (Mot. at 12, fn. 3.)

Plaintiffs also fail to explain why this Court should permit Dr. Kaplan to opine that his suggested battery of invasive testing for asymptomatic people with no cancer symptoms or diagnosis is "necessary" when he has not undertaken any independent analysis to determine whether this is the case. As explained in detail in the Motion (Mot. at 12-15), Dr. Kaplan essentially admits that he failed to apply any methodology in forming this opinion, much less a reliable one. Among other shortcomings, Dr. Kaplan has not considered whether a screening program for

probable human carcinogens, including NDEA and NDMA should be the same as the screening recommended for a known human carcinogen:

> Q. Okay. Would you make the same about say medical monitoring for a probable human carcinogen as you would for a known human carcinogen?
> A. I haven't thought of that, so I don't have an answer.

(Kaplan Dep. 112:24-113:7.) His opinions layer assumptions on top of assumptions. Dr. Kaplan has never investigated whether there is scientific literature establishing that NDMA and NDEA exposure merits medical monitoring, and instead just assumes that such literature exists (Kaplan Dep. 100:2-13); he has never used the term "LCT" before this litigation and simply assumes he understands it based on his "knowledge of the English language" (*id*. at 75:14-76:14); and he is not aware of any clinically available tests to monitor an individual's LCT. (*Id.* at 85:19-86:1).

There is also no merit to Plaintiffs' argument that Dr. Kaplan need not have a reliable basis to conclude that the proposed class members' exposure to valsartan necessitates medical monitoring because he has not been asked to opine on general causation, which Plaintiffs assert is a task given to other experts. (Opp. at 12.) Dr. Kaplan seeks to opine that the medical-monitoring program he has devised is reasonable and necessary with respect to all members of the proposed class. In order to offer such an opinion, he must have some basis to conclude that the proposed class members were exposed to sufficient levels of an alleged carcinogen to warrant, and

in fact *necessitate*, the monitoring he proposes. *See Hostetler v. Johnson Controls, Inc.*, No. 3:15-CV-226 JD, 2020 WL 5543081, at *2, *6-7 (N.D. Ind. Sept. 16, 2020) (noting that opinions that an individual faces "an increased risk of adverse health effects due to their exposure[]" to a certain chemical "each entail at least a general causation opinion" and an expert, thus, "must [] have a reliable basis upon which to opine that each individual plaintiff's exposure places that individual at an increased risk," and excluding medical-monitoring expert who failed to provide that basis). Plaintiffs' cases are not to the contrary.[1]

Dr. Kaplan's concession that there is no way to conclude whether an individual who reaches the LCT did so through exposure to valsartan, diet, or other environmental exposures also renders his opinion unreliable. (Kaplan Dep. 77:16-18, 82:20-83:5.) After all, Dr. Kaplan's medical-monitoring plan is intended to "mitigate the risks of developing cancer faced by the class of people because of their

[1] In *Patrick v. FirstEnergy Generation Corp.*, No. CIV.A. 08-1025, 2014 WL 1318017, at *5-7 (W.D. Pa. Mar. 31, 2014), the court concluded that an expert's recommendation of a health assessment study regarding allegedly toxic rain was reliably based on, *inter alia*, established scientific principles, various regulations, and scientific calculations. And in *Sullivan v. Saint-Gobain Performance Plastics Corp.*, No. 5:16-cv-125, 2019 WL 12323322, at *13 (D. Vt. July 15, 2019), the court allowed medical-monitoring opinions offered by an expert who published extensively on medical monitoring and whose methods were therefore peer reviewed and reliable. By contrast here, Dr. Kaplan has never published on medical monitoring and his proposed medical-monitoring program, which was developed solely for this litigation, has not been peer reviewed and is not based on established scientific protocols.

exposure to contaminated valsartan (who have a level of exposure greater than or equal to the LCT)….” (Kaplan Rep. at 3 (emphasis added).) Yet, Dr. Kaplan cannot even determine which patients would qualify for his proposed screening, *based on his own purported criteria for medical monitoring.* This admission, ignored in Plaintiffs’ Opposition, further undermines Dr. Kaplan’s entire opinion.

Plaintiffs’ attempt to distinguish case law cited in Defendants’ Motion is unavailing. First, Plaintiffs argue that *In re TMI Litig.*, 193 F.3d 613, 716 (3d Cir. 1999), is inapposite because, unlike the expert excluded in that case, Dr. Kaplan did not “ignore[]his own stated principles of assessment.” (Opp. at 14.) But Plaintiffs fail to address the relevant portion of the opinion cited by Defendants, which held that the expert’s methodology was unreliable because he “fail[ed] to assess the validity of the opinions of the experts he relied upon.” *In re TMI Litig.*, 193 F.3d at 715. [2] Plaintiffs also argue that *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 275 (E.D. La. 2014) is inapplicable because there, the excluded expert “copied verbatim” from other experts’ reports. But the *Hunt* court also excluded the expert

[2] Defendants have not (as Plaintiffs argue) waived any argument that Plaintiffs’ other experts’ opinions are not of the type that an expert in the field of cancer screening would rely upon by failing to raise it in their opening Motion. (Opp. at 14.) Defendants’ Motion specifically notes that Plaintiffs’ other experts’ opinions do not reliably support the opinion that all *proposed class members* are at an increased risk of cancer because of their valsartan use because none of them have endorsed or opined upon the specific LCTs proffered by Plaintiffs’ counsel to define their proposed medical-monitoring classes. (Mot. at 13, fn. 9.)

at issue because the expert failed to conduct any independent investigation or verify the data referenced in the opinions he relied upon. *Id.* (finding this to be the "crucial issue" to evaluation of reliability). Dr. Kaplan's opinions suffer from the same flaw, as demonstrated in his Report and confirmed at his deposition. And while the court in *Edmond v. Plainfield Bd. Of Educ.*, No. 11-cv-2805 KM/JBC, 2018 WL 4380991, at *6 (D.N.J. Sept. 13, 2018), allowed an expert opinion that "reference[d]" other experts, Dr. Kaplan does not merely "reference" Plaintiffs' other experts' opinions here; as discussed *supra*, he adopts them completely and without question as the basis for his own opinions. In other words, Dr. Kaplan simply serves to "parrot or act as a mouthpiece for other experts' opinions," which the *Edmond* court deemed unacceptable. *Id.*

In short, Dr. Kaplan's medical-monitoring opinions are not the product of a valid methodology because they are premised entirely on the opinions of other experts, which Dr. Kaplan has made no effort to verify or test.

2. Dr. Kaplan's Medical-Monitoring Opinions Are Unreliable Because He Failed to Consider the Risks and Benefits of the Testing He Recommends.

Even if it had been appropriate for Dr. Kaplan to assume that some or all proposed class members are at an increased risk of cancer as a result of their use of valsartan (and it was not), Dr. Kaplan failed to assess whether his protocol would actually improve outcomes for putative class members. Indeed, Dr. Kaplan concedes

that he does not have data on whether his program would reduce mortality. (Kaplan Dep., at 97:21-98:14.) Plaintiffs fail to address this concession in their Opposition; nor do they contest that Dr. Kaplan was unable to cite any published literature supporting annual screening (much less the specific array of tests he suggests) of asymptomatic patients exposed to NDMA or NDEA. (*Id.* at 100:2-13.)

Dr. Kaplan also failed to assess the risks of any of the screening tests he recommends, either generally or for particular class members. Plaintiffs offer no evidence or argument that Dr. Kaplan undertook any true risk analysis with respect to his opinions that the entire class of asymptomatic people should undergo a horde of tests and procedures on an annual or more frequent basis. Dr. Kaplan has testified that, if he were recommending screening for a patient in his clinical practice, he would conduct an individualized risk/benefit analysis, carefully weighing the risks of treatment and/or screening against the patient's own desires, the severity of their disease, and their condition. (Kaplan Dep. 51:19-52:11; *see also* 47:3-9.)[3]

Here, by contrast, in the context of litigation, Dr. Kaplan did not review any plaintiff-specific information in developing his proposed program; he based his opinion solely on his review of Plaintiffs' expert reports and selected literature. (Kaplan Dep. 34:20-35:21.) As a result, Dr. Kaplan recommends exactly the same

[3] This fundamental difference between Dr. Kaplan's methodology and his practice, without basis for such deviation, underscores why Dr. Kaplan does not have the appropriate qualifications to give this opinion. *See infra*, Part II.

tests for everyone in the purported class, regardless of their individual medical needs or risk factors. The objective of *Daubert*'s gatekeeping requirement "is to ensure the reliability and relevancy of expert testimony" by making certain that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Dr. Kaplan fails this test.

Plaintiffs argue in their Opposition that Dr. Kaplan appropriately considered the risks of his proposed program because he "is recommending only those screening tests that are already established and widely-accepted screening practices for populations with a similar risk of developing the same cancer." (Opp. at 17.) But Plaintiffs cannot refute that Dr. Kaplan failed to consider whether any supposed usefulness of his proposed screening tests with respect to the proposed class members outweighs the potential harm to them, especially given their individualized health histories. Further, Plaintiffs' insistence that all of Dr. Kaplan's proposed monitoring tests are "widely-accepted" is inaccurate. Indeed, Dr. Kaplan admits that the Galleri test, which he recommends for proposed class members as part of his proposed medical-monitoring program, is not FDA approved (Kaplan Dep. 111:21-23) and that he knows of no guidelines or organizations that support annual Galleri testing. (*Id.* at 88:7-10.) Further, Dr. Kaplan testified that he would use a prostate-specific antigen blood test ("PSA") on any proposed class member, including a 90-

year-old patient. (*Id.* 73:3-5.) This is indisputably outside of established screening guidelines, as the U.S. Preventive Services Task Force, an independent, volunteer panel of national experts in disease prevention and evidence-based medicine, does not recommend PSA testing for patients older than 70 years of age.[4] Thus, a PSA test on a 90-year-old man is nowhere near "within the limits of acceptable risk for the general population." Yet, Dr. Kaplan offers no basis for deviating from these standards. Dr. Kaplan also fails to explain why the increased risk associated with some of the procedures he recommends is justified with respect to the proposed class members. Plaintiffs' assertion that "[m]any of [sic] procedures that Dr. Kaplan recommends are non-invasive and carry very little risk" (Opp. at 17 at n. 9) is supported by nothing other than Dr. Kaplan's *ipse dixit* and does not constitute a reliable weighing of the potential risks of his medical-monitoring plan with respect to the specific proposed class members against its purported benefits.[5]

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[4] *See* US Preventative Services Taskforce Final Recommendation Statement, "Prostate Cancer: Screening" 2018, *available at* https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prostate-cancer-screening, last accessed June 8, 2022.

[5] Plaintiffs urge the Court to presume Defendants have no issue with physical consequences of the Galleri or Cologuard tests, on the supposed ground that Defendants "failed to mention these tests at all in their motion while lumping them in with more invasive tests[.]" (*Id.*) Again, this is untrue. As noted above, Defendants specifically objected to Dr. Kaplan's recommended use of the Galleri test, which is not FDA approved (Mot. at 2, 5, 21), and similarly note that the bevy of tests proposed by Dr. Kaplan, which includes the Cologuard test, carry significant risks (*id*. at 5, 16-17).

Plaintiffs' effort to distinguish the authorities cited by Defendants also fails. Contrary to Plaintiffs' assertion, *In re Paoli* addressed questions nearly identical to those before this Court with respect to Dr. Kaplan, including whether an expert's prescription of a "battery of periodic screening tests" for asymptomatic patients sufficiently takes into account the potential risks and benefits of those procedures. No. 86-2229, 2000 WL 274262, at *8 (E.D. Pa. Mar. 7, 2000). In that case, the court found that "by prescribing numerous screening tests without considering the information that is critical to an assessment of their necessity, [the expert's] approach creates a great potential for error in the screening process." *Id*. at *9. The same is true here. Plaintiffs cannot refute that Dr. Kaplan did not perform an analysis of the risks and benefits of his proposed program, much less consider whether the supposed usefulness of his proposed tests is outweighed by the potential harm to the proposed class members.

For these reasons, Plaintiffs' argument that Defendants' criticisms boil down to "a battle-of-the-experts issue" that should be resolved by the jury fails. (Opp. at 16.) A "battle of the experts" can be resolved by the jury only if both experts' opinions are based on reliable, admissible methodologies. *See e.g., Lithuanian Commerce Corp. v. Sara Lee Hosiery*, 179 F.R.D. 450, 458-60 (D.N.J. 1998). Dr. Kaplan's failure to *consider* whether the potential risks of those tests would outweigh any benefit for each proposed class member is not a jury issue; rather, his

failure to conduct such an inquiry renders his opinion unreliable, and therefore inadmissible under *Daubert*.

In a final effort to argue that Dr. Kaplan's opinions are based on a reliable methodology, Plaintiffs criticize the rebuttal opinions offered by defense experts Dr. Teitelbaum and Dr. Chan.[6] Notably, both defense experts base their opinions on approved national standards for screening. (*See generally* Mot. Ex. D, Report of Ursina Teitelbaum, M.D.) Dr. Kaplan, on the other hand, proposes his own screening standards, which have not been approved or vetted by the major oncologic organizations that develop such cancer screening protocols, and he provides no data to support them.

* * * * * *

For all of these reasons, Plaintiffs have failed to meet their burden to demonstrate that Dr. Kaplan's opinions that his monitoring program is "reasonable and necessary" for the entire proposed class are based on a reliable methodology and, for this reason alone, this Court should exclude his opinions.

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[6] Dr. Teitelbaum's and Dr. Chan are highly qualified to rebut Dr. Kaplan's testimony. Dr. Teitelbaum is an oncologist who is well acquainted with the risks and benefits of cancer development versus cancer screening. Dr. Chan studies health policy with a focus on treatment decisions and clinical practice guidelines, as well as the effects of health policies and systems of care on the general public. He is eminently qualified to opine as to the risks and benefits of the type of program Dr. Kaplan proposes. Notably, Plaintiffs have not moved to exclude the opinions of Drs. Teitelbaum or Chan, and their argument as to the supposed "weakness" of their qualifications is therefore moot.

II. PLAINTIFFS CANNOT REFUTE THAT DR. KAPLAN IS NOT QUALIFIED TO CONSTRUCT A PUBLIC MONITORING PROGRAM.

Plaintiffs' argument that Dr. Kaplan is qualified to provide medical-monitoring opinions in this case because he is an oncologist who has treated "tens of thousands of patients with cancer" should also be rejected.[7] (Opp. at 9.) While Defendants do not dispute that Dr. Kaplan has expertise as a practicing oncologist with respect to the diagnosis and treatment of cancer, he has no experience that would allow him to devise a reliable public monitoring program for a large population of asymptomatic individuals . "One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc*., 43 F.3d 1311, 1317 (9th Cir. 1995). Plaintiffs offer no evidence that Dr. Kaplan's proposed program grew "naturally and directly" out of

[7] Plaintiffs also suggest that Dr. Kaplan's opinions are admissible under the *reliability* prong of Rule 702 based on his experience as an oncologist. But, as Plaintiffs note in their Opposition, reliability rests in part on "whether a method has been subject to peer review," "whether the method is generally accepted," and "the qualifications of the expert witness testifying based on the methodology." *Geiss v. Target Corp.*, No. 09-2208 RBK/KMW, 2013 WL 4675377, at *4 (D.N.J. Aug. 30, 2013). Dr. Kaplan's program is not peer reviewed, but rather is an entirely new program that is based on exposure to chemicals not included in accepted screening guidelines, and Dr. Kaplan has never designed a public medical-monitoring program. His experience is insufficient to meet the reliability requirement.

any research conducted independent of this case, nor out of his clinical experience.

Plaintiffs cannot dispute that, while Dr. Kaplan treats cancer patients, he does not treat asymptomatic patients with carcinogenic exposures (or exposures to probable carcinogens) who have no cancer diagnosis in an attempt to monitor them for potential future cancers. For instance, Dr. Kaplan does not treat or recommend monitoring for every individual who smokes cigarettes. (Kaplan Dep. 110:1-111:5.) And even for those patients he does see who have been exposed to a known human carcinogen like tobacco (which has a greater, established cancer risk than a "probable" human carcinogen like NDMA or NDEA), he has ***never*** proposed a monitoring program for those patients, and has never proposed or designed ***any*** public medical-monitoring program. (Kaplan Dep. 44:14-16, 110:18-111:5.) In fact, as explained in the Motion, Dr. Kaplan has zero experience constructing a public monitoring program outside the context of this litigation.[8] Plaintiffs stress in their

[8] Plaintiffs attempt to distinguish *Allgood v. GMC*. No. 1:20-cv-1077-DFH-TAB, 2006 U.S. Dist. LEXIS 70764 (S.D. Ind. Sept. 18, 2006), on grounds that Dr. Kaplan is a licensed oncologist and the excluded expert there was not. But the expert in *Allgood*'s lack of oncology training was only one factor considered by the court in excluding his testimony. The court also noted that the expert was unqualified because, like Dr. Kaplan, the expert had never "designed, endorsed, or implemented a medical monitoring program on his own before." *Id.* at *92. Plaintiffs similarly dismiss *Arias v. DynCorp*, 928 F. Supp. 2d 10, 25 (D.D.C. 2013), arguing that, unlike in that case, there is a "patently obvious connection between Dr. Kaplan's education and study of cancer metastasis and screening for cancer." Opp. at 10. But in *Arias*, the court considered the expert unqualified to "opine[] that a medical "monitoring regime [was] necessary and indicated" for the plaintiffs despite his having had a

Opposition that Dr. Kaplan has recommended cancer screening for certain of his "high-risk" patients based on their individual needs (Opp. at 9), but they cannot dispute that Dr. Kaplan has never designed or recommended anything like the specialized screening program he proposes for a large group of asymptomatic individuals here, nor has he ever published on the subject of medical monitoring generally. (Kaplan Dep. at 44:14-18; *see also id.* at 106:23-107:5 ("Q. And, Doctor, have you ever—have you ever crafted a medical monitoring plan such as this for litigation before? A. No. Q. Have you ever published on medical monitoring? A. I have not.").) Accordingly, Plaintiffs fail to establish that Dr. Kaplan is qualified to, for his first time ever and only for this litigation, opine that the proposed medical-monitoring program is necessary or even appropriate for all proposed class members.

CONCLUSION

For the foregoing reasons, and those stated in Defendants' Motion, Defendants request that the Court exclude Dr. Kaplan's opinions in their entirety.

"lengthy career in occupational and environmental medicine" which involved "'render[ing] thousands of diagnoses and opinions on the causation of disease involving complex issues of toxic exposures' and, through his clinical practice, conduct[ing] 'environmental and occupational risk assessment and toxic exposure evaluations.'" *Arias*, 928 F. Supp 2d at 20, 25. Plaintiffs have not established that Dr. Kaplan's experience as a practicing oncologist qualifies him to certify a public medical-monitoring program for thousands of patients without any cancer diagnosis or symptoms.

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CERTIFICATE OF SERVICE

I, Kate Wittlake, an attorney, hereby certify that on June 8, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

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